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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,073	07/30/2001	Richard O. Hilson	10004450-1	2655

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EXAMINER	
SODERQUIST, ARLEN	

ART UNIT	PAPER NUMBER
1743	4

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,073	HILSON ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-53 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holen. In the patent Hollen teaches a reaction cartridge and carousel for a biological analyzer. A semi-automated biological sample analyzer and subsystems are provided to simultaneously perform a plurality of enzyme immuno assays for human IgE class antibodies specific to a panel of preselected allergens in each of a plurality of biological samples. A carousel is provided to position and hold a plurality of reaction cartridges. Each reaction cartridge includes a plurality of isolated test sites formed in a two dimensional array in a solid phase binding layer contained within a reaction well which is adapted to contain a biological sample to be assayed. The carousel and cartridges contain structures which cooperate to precisely position the cartridges in each of three separate dimensions so that each cartridge is positioned uniformly. An optical reader operating on a principle of diffuse reflectance is provided to read the results of the assays from each test site of each cartridge. Also provided is a subsystem which provides predetermined lot-specific assay calibration data which is useful for normalizing the results of various assays with respect to predetermined common standard values. The biological sample analyzer (10) includes a processing chamber (11) in which to test biological samples. A chamber door (12) is preferably hingedly mounted to the analyzer overlying the chamber to selectively close off and provide access thereto. Inset into the chamber door is a translucent viewing window (14$ which allows an operator to view the activity within the processing chamber. The

window preferably includes a reagent addition port (16) through which reagents can be introduced into the chamber without opening the chamber door. The processing chamber contains a holding rack, preferably in the form of a rotatable carousel (18) which holds and conveys reaction cartridges (80) in order to position the cartridges at stations to receive sample and selected reagents and for reading test results therefrom, and to provide agitation required for processing the samples. the carousel also functions as a very precise optical bench, accurately positioning each reaction cartridge relative to an optical reader (32) to facilitate accurate and repeatable reading of test results directly from the cartridges. The carousel is preferably disposed on a tilted axis. Rotation of the carousel about this tilted axis provides desirable agitation of the fluids in a reaction well (86) of each reaction cartridge thereby promoting faster and more complete reactions and allowing the use of smaller volumes of sample and reagents than has previously been possible. A wash/waste unit preferably is provided and includes chambers (22,24) for holding wash solution to be added to the reaction cartridges and waste fluid aspirated from the reaction cartridges. A wash manifold (26) functions both as a cover for the chambers and as a mount for wash tubing and waste tubing (21,23). Wash and waste fluids are caused to flow through wash and waste tubing by means of peristaltic pumps (25,27). Wash and waste fluids are preferably introduced into and removed from the reaction wells of reaction cartridges mounted on carousel by means of a fluid probe (28) which is mounted proximate the free end of a horizontal, pivotally-mounted probe arm (33). In a preferred embodiment, fluid access to a reaction cartridge is provided when the carousel conveys the reaction cartridge to a preselected wash of the biological analyzer. At this position, the tilt of the carousel causes any fluid in the reaction well to gravitate towards a corner of the reaction well for removal by aspiration with the fluid probe. The preferred reaction cartridge includes a test card (82) which includes an array of test sites (84) preferably in close proximity to each other. The test card is contained within a reaction well which is defined by a well wall (88). The reaction well is preferably provided with a removable, preferably transparent well cover (90) which preferably includes a reagent port (92) to facilitate the delivery and removal of fluids from the reaction well. The reaction cartridge also preferably includes code means (94) such as an optical bar code which is attached to or printed directly on the flat surface (91) of the reaction cartridge. The bar code is adapted to be read by the optical reader or by other conventional optical reader means

and includes a lot code which is advantageously used to access stored assay calibration data corresponding to the particular reaction cartridge being tested. The test card is preferably a laminate structure comprising a binding layer (83) adhered to a non-absorbent substrate (85) using an adhesive such as a double-sided adhesive film (87). The capture reagent or assay binding component include any compound capable of directly or indirectly binding a desired component from a biological test sample. For example, a capture reagent or assay binding component may include antibodies, antigens, biotin, antibiotin, avidin, lectins, or peptide sequence probes, as well as combinations of the above (column 15 lines 9-19). The capture reagent can also be DNA for hybridization assays (column 13, lines 52-54). Columns 31-33 discuss the system control architecture of the analyzer including a bus (320). Columns 33-38 gives an explanation of the steps involved in the analysis including the manual steps of adding sample, conjugate, substrate and removing the cover. Holen does not teach removing the cover prior to adding fluids. However, it would have been obvious to one of ordinary skill in the art that removal of the cover to add fluid was possible if one were not concerned with the sealing advantages taught by Holen.

3. Claims 1-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holen as applied to claims 48-53 above, and further in view of Panetz. Holen is a semi-automated device and therefore requires operator intervention to place the reaction cartridge on the carousel and add fluids. As such Holen does not teach an input means or an output means.

In the patent Panetz teaches apparatus for automatically separating a compound from a plurality of discrete liquid specimens. In columns 1-2 Panetz discusses disadvantages with prior methods for doing this which include operator intervention to change a first batch of separating devices and introduce a second set of separating devices in a batch processing device. This problem is overcome by addition of structure to add new separation devices to the rotating carousel (figures 4-5 and their associated discussion) and remove the from the carousel after the separation is complete (figure 15 and its associated discussion). The device also has means to automatically add fluids to the separation devices. These mechanisms are taught as reducing the operator interface with the device, helping to prevent contamination and facilitating the continuous operation of the device (columns 2-4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate input and output means into the Holen device and method because of the reduced the operator interface with the device, reduced contamination and the ability for continuous operation of the device as taught by Panetz.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional art relates to means for processing biological samples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Arlen Soderquist

September 30, 2003

ARLEN SODERQUIST
PRIMARY EXAMINER